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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/612,012	07/03/2003	Karl Guegler	CL000968DIV2	6674

25748 7590 07/27/2006

CELERA GENOMICS  
ATTN: WAYNE MONTGOMERY, VICE PRES, INTEL PROPERTY  
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EXAMINER

XIE, XIAOZHEN

ART UNIT PAPER NUMBER

1646

DATE MAILED: 07/27/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/612,012	GUEGLER ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Xiaozhen Xie	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 22 May 2006.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 3 and 24-36 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 3, 25, 27, 29, 31 and 33 is/are allowed.
- 6) ☒ Claim(s) 24, 26, 28, 30, 32, 34 and 36 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 07/03/2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date: _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date: _____  | 6) <input type="checkbox"/> Other: _____                                    |

## **DETAILED ACTION**

### ***Response to Amendment***

Applicant's amendments of the specification received on 22 May 2006 have been entered.

Claims 3 and 24-36 are pending and under examination in this office action. The text of those sections of Title 35, U.S. Code, not included in this action can be found in a prior office action.

### ***Specification***

The objections of the specification for failing to update the cross-reference to prior applications, and for not describing the claimed invention in the abstract, are withdrawn in response to applicant's amendments of the specification.

### ***Sequence Rules***

Upon further reviewing the drawings, it appears that the sequences in the figures do have sequence identifiers. Therefore, the Instant application is in compliance with the sequence rules.

### ***Claim Rejections Withdrawn***

The rejection of claims 3 and 24-36 under 35 U.S.C. 102(e) as being anticipated by Rubenfield et al. (U. S. Patent No: 6,551,795 B1), is withdrawn in response to Applicant's argument that an antibody that binds to both the polypeptide of Rubenfield

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et al. and to the instant SEQ ID NO: 2 would not be an antibody that selectively binds SEQ ID NO: 2.

***Claim Rejections Maintained***

The rejection of claims 24, 26, 28, 30, 32, 34 and 36 under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement, is maintained for reasons of record in the previous office action (22 February 2006).

Applicant argues that the claims are directed to an antibody that binds selectively to a polypeptide comprising SEQ ID NO: 2, and that an antibody that binds sequences flanking the polypeptide of SEQ ID NO: 2 would not be considered an antibody that binds selectively as such an antibody would bind to the flanking sequences regardless of the sequences that flank. Applicant argues that antibodies that bind selectively to a polypeptide comprising SEQ ID NO: 2 would only include antibodies that recognize epitopes contained in the sequence of SEQ ID NO: 2.

Applicant's arguments have been fully considered but have not been found to be persuasive.

As stated in the previous office action, the instant claims are directed to an isolated antibody that selectively binds to a polypeptide, wherein the amino acid sequence of said polypeptide comprises SEQ ID NO: 2. The specification, however, does not provide teachings for antibodies that bind to sequences that may flank SEQ ID NO: 2 in a polypeptide comprising SEQ ID NO: 2. The specification has only provided teachings for an isolated antibody that selectively binds to a polypeptide consisting of SEQ ID NO: 2. Antibodies that recognize epitopes in the flanking sequences of SEQ ID

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NO: 2 would selectively bind to a polypeptide that comprises SEQ ID NO: 2. The specification fails to provide teachings as to what these sequences will be and how long these sequences will be. Thus, the claims encompass a genus of molecules, which vary substantially in composition, and could have very different structural and functional characteristics from the antibody that Applicant has disclosed.

The rejection of claims 24, 26, 28, 30, 32, 34 and 36 under 35 U.S.C. § 112, first paragraph, as failing to comply with the enablement requirement, is maintained for reasons of record in the previous office action.

Applicant argues that the claims are directed to an antibody that binds selectively to a polypeptide comprising SEQ ID NO: 2, and that an antibody that binds sequences flanking the polypeptide of SEQ ID NO: 2 would not be considered an antibody that binds selectively as such an antibody would bind to the flanking sequences regardless of the sequences that flank. Applicant argues that antibodies that bind selectively to a polypeptide comprising SEQ ID NO: 2 would only include antibodies that recognize epitopes contained in the sequence of SEQ ID NO: 2.

Applicant's arguments have been fully considered but have not been found to be persuasive.

As stated supra, the instant claims are directed to an isolated antibody that selectively binds to a polypeptide, wherein the amino acid sequence of said polypeptide comprises SEQ ID NO: 2. The specification, however, does not provide teachings for antibodies that bind to sequences that may flank SEQ ID NO: 2 in a polypeptide

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comprising SEQ ID NO: 2. The specification has only provided teachings for an isolated antibody that selectively binds to a polypeptide consisting of SEQ ID NO: 2. Antibodies that recognize epitopes in the flanking sequences of SEQ ID NO: 2 would selectively bind to a polypeptide that comprises SEQ ID NO: 2. Since the specification does not define what these sequences will be, one of skill in the art would evaluate all non-exemplified antibodies for binding activity. Thus, undue experimentation would be required for the artisan to make and use the invention as broadly claimed.

### ***Conclusion***

CLAIMS 3, 25, 27, 29, 31 AND 33 ARE ALLOWABLE.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Xiaozhen Xie whose telephone number is 571-272-5569. The examiner can normally be reached on M-F, 8:30-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary B. Nickol, Ph.D. can be reached 571-272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Xiaozhen Xie, Ph.D.  
July 13, 2006

GARY B. NICKOL, PH.D.  
SUPERVISORY PATENT EXAMINER  
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